

28)-(129-160), or a single ultimate species of a fragment of residues 1-160 which retains function (as in claim 103), a fragment of ≥ 30 nucleotides of SEQ ID NO:3, a fragment of ≥ 30 nucleotides of the complement of SEQ ID NO:3, and a nucleic acid which hybridizes to the complement of nucleotides 1-860 of SEQ ID NO:3.

(See, Paper No. 10, Page 2, Lines 14-24.)

In order to be fully responsive, Applicants hereby elect, with traverse, a nucleic acid molecule comprising a polynucleotide encoding a protein consisting of amino acids 28-160 of SEQ ID NO:4: (Claim 79). Applicants reserve the right to file one or more divisional applications directed to non-elected inventions should the additional restriction requirement be made final. In such a case, Applicants retain the right to petition from the additional restriction requirement under 37 C.F.R. § 1.144.

Applicants respectfully traverse and request the withdrawal of the requirement for further restriction.

As a threshold matter, Applicants point out that MPEP § 803 lists the criteria for a proper restriction requirement:

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent (MPEP § 806.04 – § 806.04(i)) or distinct (MPEP § 806.05 – § 806.05(i)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

Thus, even assuming, *arguendo*, that the sequences listed by the Examiner represent distinct or independent inventions, restriction remains improper unless it can be shown that the search and examination of these sequences would entail a “serious burden.” See M.P.E.P. § 803. In the present situation no such showing has been made.

The Examiner alleges that

Although the classifications for these various nucleic acids are overlapping, for instance 536/23.1, each represents a patentably distinct product with distinct physical and functional characteristics. Further the search for more than one product would be burdensome, because each is claimed not by nucleic acid sequence, but by the sequence of the protein encoded thereby, and requires a search of the corresponding region of SEQ ID NO:1 [sic] as well as a ‘reverse

translation' search of the corresponding region of SEQ ID NO:2 [sic], such that each individual sequence requires two sequence searches which are not required for any of the other sequences, or alternatively by virtue of comprising only a small portion of a disclosed nucleic acid, which requires a separate "word search" of the nucleic acid databases, or by claiming nucleic acids which 'hybridize' to a disclosed nucleic acid, which requires a broader search of the nucleic acid databases. Due to the use of 'comprising' language, it cannot even be said that the search for nucleic acids encoding amino acids 1-160 of SEQ ID NO:4 would reveal art pertaining to, for instance a nucleic acid *comprising* a region encoding amino acids 19-27 of SEQ ID NO:4, as the latter could be found embedded in a completely different protein. Accordingly, restriction is proper.

(See, Paper No. 10, Page 3, Lines 3-16, emphasis in original.)

Applicants disagree and submit that an art search with a nucleic acid comprising a polynucleotide encoding a protein consisting of amino acids 28-160 of SEQ ID NO:4 would be largely overlapping with that for a nucleic acid molecule comprising a polynucleotide encoding amino acid residues 1-160, 10-160, 1-150, 1-140, 28-129, 57-64, 72-77, 99-105, 121-128, 19-27, 30-38, 40-48, 58-67, 105-113, 129-137, 151-159, (57-64 *and* 151-159) of SEQ ID NO:4; a nucleic acid molecule comprising a polynucleotide encoding amino acids (1-28)-160, 1-(129-160), or (1-28)-(129-160) of SEQ ID NO:4; a nucleic acid molecule comprising a polynucleotide encoding amino acids 1-160 of SEQ ID NO:4 which retains function; a nucleic acid molecule comprising at least 30 nucleotides of SEQ ID NO:3; a nucleic acid molecule comprising at least 30 nucleotides of the complement of SEQ ID NO:3; and a nucleic acid molecule comprising a polynucleotide which hybridizes to the complement of nucleotides 1-860 of SEQ ID NO:3. Thus, the search and examination of all claims which encompass a nucleic acid comprising a polynucleotide encoding a protein consisting of amino acids 1-160, 10-160, 28-160, 1-150, 1-140, 28-129, 57-64, 72-77, 99-105, 121-128, 19-27, 30-38, 40-48, 58-67, 105-113, 129-137, 151-159, (57-64 *and* 151-159) of SEQ ID NO:4; a nucleic acid molecule comprising a polynucleotide encoding amino acids (1-28)-160, 1-(129-160), or (1-28)-(129-160) of SEQ ID NO:4; a nucleic acid molecule comprising a polynucleotide encoding amino acids 1-160 of SEQ ID NO:4 which retains function; a nucleic acid molecule comprising at least 30 nucleotides of SEQ ID NO:3; a nucleic acid molecule comprising at least 30 nucleotides of the complement of SEQ ID NO:3; and a

nucleic acid molecule comprising a polynucleotide which hybridizes to the complement of nucleotides 1-860 of SEQ ID NO:3 would not entail a serious burden.

In addition, Applicants respectfully remind the Examiner that upon allowance of a generic claim, Applicants will be entitled to the consideration of additional "species" which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. MPEP § 809.02(a).

No,
Nota
SPP
elect.

Applicants respectfully point out that the Examiner has not disclosed any statutory or regulatory basis for requiring the election of an individual sequence within the previously elected Invention II. Assuming *arguendo* that the Examiner is requiring an election of the members of the Markush-type claims, Applicants respectfully point out that MPEP § 803.02 requires that "[i]f the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits." Applicants submit that the members of the Markush groups of the pending claims are sufficiently few in number and very closely related, as they are all nucleic acid molecules encoding different portions of the same amino acid sequence, so that a search of all of the members may be made without a serious burden, contrary to the Examiner's position. Moreover, even assuming that examination of the entire claim would present a serious burden, MPEP § 803.02 states that "[f]ollowing election, the Markush-type claim will be examined fully as to the elected species and further to the extent necessary to determine patentability." If no prior art is found "that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended." *Id.* (emphasis added).

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Applicants submit that the claims encompass nucleic acids encoding different fragments of the same protein, rather than different proteins as contemplated by § 803.04. "[N]ucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together." Thus, Applicants respectfully submit

that the present requirement for further restriction is improper. However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why ten sequences are unreasonable in the present case.

Thus, Applicants respectfully request that the further restriction within the formerly presented Invention II be withdrawn so the restricted subject matter can be examined together.


Applicants respectfully point out that the provisionally elected subject matter is overlapping in scope to the pending claims, particularly given that all of the claims are directed to nucleic acid molecules comprising polynucleotides encoding regions of SEQ ID NO:4 (or the corresponding deposited clone). Nevertheless, to the extent that the Examiner requests that Applicants "point out which claims correspond to the elected invention" (see, Paper No. 10, Page 3, Line 1-2), Applicants point out that claim 79 is particularly directed to the provisionally elected subject matter of a nucleic acid molecule comprising a polynucleotide encoding a protein consisting of amino acids 28-160 of SEQ ID NO:4.

Conclusion

Applicants respectfully request that the above-made remarks be entered and made of record in the file history of the instant application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Date: SEPTEMBER 18, 2001


Janet M. Martineau (Reg. No. 46,903)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
301-315-2723 (telephone)

KKH/JMM/CCB.